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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,280	03/04/2004	Michael R. Bowman	WYE-027	3906

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EXAMINER	
LIN, JERRY	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/792,280	BOWMAN ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,8,10,12-14 and 21-25* is/are pending in the application.

4a) Of the above claim(s) *23 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,8,10,12-14,21,22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *23-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed January 16, 2007, have been fully considered and they are deemed to be persuasive in part. Amendments to the claims have necessitated new grounds of rejection. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

2. Newly submitted claims 23 and 25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

As in the species election requirement mailed June 9, 2006, Applicants were required to elect one type of agent in species C because the agents are different chemicals. Since the agents are different chemicals, the components do not overlap in scope and have a materially different design. Thus the agents are distinct.

Since applicant has received an action on the merits for the originally elected invention, claim 23 and 25 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the Claims

Claims 1, 4, 6, 8, 10, 12-14 and 21-24 are under examination.

Claims 2, 3, and 15-20 are cancelled.

Claims 5, 7, 9, 11, 23 and 25 are withdrawn as being drawn to an unelected group.

Information Disclosure Statement

3. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 21, 22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Ochoa et al. (US 2004/0057926).

The instant claims are drawn to a method of administering therapeutically effective amount of an agent to a mammal with a chronic obstructive pulmonary disease wherein the agent inhibits the activity of CAT2 in a tissue affected by the disease.

Regarding claims 21, 22, and 24, Ochoa et al. teach administering an therapeutically effective amount of lysine (Abstract; Pages 1-2, paragraph 0013; Page 2, paragraph 0016) which inhibits a component of the arginine metabolic pathway such as a cationic amino acid transporter 2 (Page 2, paragraph 0016) for treating a respiratory disease such as chronic obstructive pulmonary disease (Page 6, paragraph 0063) to a mammal (page 1, paragraph 0013).

Response to Arguments

The Applicants have submitted the instant claims as new claims. Although these new claims have not been rejected previously, the Applicants also provided arguments with the new claims. The arguments presented are that the Ocha et al. reference is not

available as prior art against the new claims, because the provisional the instant reference relies upon does have the same forms as the instant reference. However, in order for a patent application to claim priority to its provisional, the patent application needs only to find support in the provisional. The provisional need not be exactly the same as the patent application. For example, on page 2 of the provisional, the provisional supports the instant reference by teaching treating disease where there is chronic inflammation such as chronic obstructive pulmonary disease (page 2, paragraph 0006).

This rejection is necessitated by amendment.

6. Claims 1, 4, 6, 8, 12-14, 21, 22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothenberg et al. (US 2003/0166562).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with asthma wherein the agent inhibits an activity or expression of a component of an arginine metabolic pathway that is not NOS. The applicants have incorporated the limitation so of claims 2 and 3 into claim 1. However, the limitations of claim 3 have been amended into claim 1 to include only asthma and chronic airway remodeling, but not chronic obstructive pulmonary disease. Given this change, the instant rejection is necessitated by amendment.

Rothenberg et al. teach a method that includes administering a therapeutically effective amount of an agent to a mammal with asthma which inhibits CAT2 or the gene encoding for CAT2 (page 2, paragraphs 0016-0019); wherein one possible agent is

capable of binding to a polynucleotide encoding the component by an antisense mechanism (page 12, paragraph 0069 - page 13, paragraph 0071); wherein another possible agent is lysine or a cationic polypeptide for inhibiting CAT2 (page 13, paragraph 0075, page 2, paragraph 13); where the mammal is human (page 2, paragraph 0016; page 4, paragraph 0041).

This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenberg et al. (US 2003/0166562) in view of Hannon (Nature (2002) volume 418, pages 244-251).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with asthma where an agent such as siRNA inhibits the activity or expression of a component of an arginine metabolic pathway and where the component is not a nitric oxide synthase.

Rothenberg et al. is applied to claims 1 and 8 as above.

However Rothenberg et al. do not specifically teach using siRNA.

Regarding claim 10, Hannon teaches that siRNA may be synthesized to target and silence genes of interest (page 245; page 250).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of Rothenberg et al. with Hannon to create siRNA for the purpose of inhibiting the production of CAT2. Rothenberg et al. teach that the inhibition of CAT2 expression via antisense mechanisms is desirable to treat asthma (page 14, paragraphs 0082 and 0091; page 16, paragraph 0012). However, Hannon teaches that siRNA is a much more potent inhibitor of gene expression than sense or antisense RNAs (page 244, right column). Thus one of ordinary skill in the art seeking to inhibit CAT2 mRNA would be motivated to use siRNA for the increased potency of siRNA over sense or antisense RNAs.

This rejection is necessitated by amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL

MICHAEL BORIN, PH.D
PRIMARY EXAMINER